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## PATENT COOPERATION TREATY

PCT

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P31175WO/JLWM	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP01/00817	International filing date (day/month/year) 25/01/2001	Priority date (day/month/year) 22/12/2000
International Patent Classification (IPC) or national classification and IPC A61M5/50		
<p style="text-align: right;"><b>RECEIVED</b> MAY 23 2003 TECHNOLOGY CENTER R3700</p>		
Applicant NICODEL S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  19/07/2002	Date of completion of this report  14.03.2003
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Vänttinen, H  Telephone No. +49 89 2399 7442



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP01/00817

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

### Description, pages:

1-20 as originally filed

### Claims, No.:

1-56 as originally filed

### Drawings, sheets:

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

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☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 50-52.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 50-52 are so unclear that no meaningful opinion could be formed (*specify*):  
**see separate sheet**

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

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- ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-15.

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes: Claims 6,7,12,13,15
	No: Claims 1-5, 8-11, 14
Inventive step (IS)	Yes: Claims 6,7,12,13
	No: Claims 1-5, 8-11, 14,15
Industrial applicability (IA)	Yes: Claims 1-15
	No: Claims

### 2. Citations and explanations **see separate sheet**

**1 Concerning Item III**

The subject-matters of claims 50-52 cannot be examined in respect of Article 33(2)-(4) PCT, because it is unclear what technical features of the device are defined by referring to the drawings.

**2 Concerning Item IV**

2.1 This Examination Authority agrees with the objection put forward by the Search Authority as to lack of unity. Claims 1, 16, 23, 26 and 53 do not meet the requirements of Rule 13 PCT, because they do not appear to have any common or corresponding special technical features as required in Rule 13.2 PCT, the reasons being as follows:

2.2 In the light of FR-A-2 718 358 (D1) claims 1 and 16 cannot have any special technical feature, because D1 appears to disclose all the features of said claims.

2.3 In the light of D1, claim 23 is considered to have the following special technical feature: A) the needle is a push-fit **in the bore** of the retainer.

2.4 In the light of D1, claim 26 has the following special technical features:  
B) the needle assembly is removable insertable **through** the open front end of the neck portion **into** the neck portion of the fluid container.

2.5 In the light of D1, claim 53 has the following special technical features:  
C) an eccentrically located neck and D) means for preventing rotation of the plunger in the barrel.

2.6 In the light of the above, claims 1, 16, 23, 26 and 53 cannot have any common or corresponding special technical features and their subject-matters are therefore not so linked as to form a single general inventive concept. Thus, the present set of claims is considered to relate to **five** different possible inventions covered by the following groups of claims: i) claims 1-15, 38-49, ii) claims 16-22, 37, iii) claims 23-25, 37-49, iv) 26-37 and v) 53-56.

2.7 The applicant has neither paid the corresponding additional examination fees nor limited the application according to one of the possible inventions i) to v). Consequently, the Preliminary Examination Report is drawn up for the claims 1-15.

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2.8 For the entrance into the regional phase, the attention of the applicant is drawn to Article 82 EPC. In the European phase the application may include only one invention. Other inventions are to be excised from the claims, the description and the drawings. The excised subject-matter may be made the subject of one or more divisional applications. The divisional applications must be filed directly at the European Patent Office in Munich or its branch at The Hague and in the language of the proceedings relating to the present application, cf. Article 76(1) and Rule 4 EPC.

**3 Concerning Item V**

3.1 D1 discloses a locking mechanism comprising a retainer part (210) having a fixed formation (218) engageable with a second formation (112) located on a body part (100) of a medical sharp device, a connector part (206) movable relative to the body part to mutually engage the connector part (206) and the retainer part (210). The connector part can alter the relative engagement between the first and second formations (218, 112) to release the retainer part from the body part (see Figs. 2a and 2b). Also US-A-4 904 242 (D2) and US-A-5 047 016 (D3) appear to disclose a locking mechanism which falls under the wording of claim 1. Thus, the subject-matter of claim 1 does not meet the requirement of Article 33(2) PCT.

3.2 Also the technical features of 2-5, 8-11 and 14 appear to be disclosed by D1, D2 and/or D3. Thus, the subject-matters of said claims do not meet the requirement of Article 33(2) PCT.

3.3 The subject-matters of claims 6, 7, 12, 13 and 15 appear not to be obvious for the skilled person on the basis of the documents cited in the Search Report. Thus, said claims appear to meet the requirements of Article 33(2) and (3) PCT.

3.4 The industrial applicability (Article 33(4) PCT) of the locking mechanism according to claims 1-15 is self-evident.